K002431

OCT 2 4 2000

Envision's Elran01 System 510(k) Summary

Name of Device	ELRAN 01 Stereoscopic Laparoscope
Common or Usual Name	Laparoscope system
Classification Names	Laparoscopes and accessories (21 C.F.R. § 876.1500)
Product Codes	GCJ
Submitter	Envision Advanced Medical Systems Ltd. 20 Hamagshimim Street P.O. Box 7149 Petach Tikva 49348 Israel
Phone:	011-972-3-924-4339
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Contact Person:	Michael Mizrachi
Date Prepared:	August 1, 2000

Predicate Devices

Trade Name	Manufacturer
Stereo View System	Intuitive Surgical
Operating Laparoscope	Richard Wolf
Laparocam	Karl Storz

Intended Use

The Elran01 system is intended for viewing internal surgical sites during general endoscopic and laparoscopic surgical procedures.

Substantial Equivalence

The Elran01 system combines a rigid laparoscope with internal optical components, a computer workstation image processing unit to generate images, and an image display system intended for viewing internal surgical sites during general endoscopic and laparoscopic surgical procedures. The Elran01 system is substantially equivalent to several currently marketed devices that capture and display images intended viewing internal surgical sites during general endoscopic and laparoscopic surgical procedures.

The Elran01 system and the predicate devices all provide rigid laparoscopic insertion tubes that are inserted into the patient's body through surgically prepared access sites. Once inserted, an illumination source is connected to the laparoscope to provide light to the surgical site. Optical units and camera systems are employed to capture images of the surgical site and transmit the images via a cable to an image processing and display unit.

The principal differences between the Elran01 system and the predicate devices involve the way in which two channel images are generated by the optics component and transmitted by the distal electronics component. The Elran01 system's two channel image is created by the optical array, a series of high-quality lenses, by simultaneously acquiring images of the surgical site from two slightly different viewing angles. Both images are then detected by the CCD camera. By recording the angle associated with each image as it strikes the CCD camera, the distal electronics component is able to transmit both image channels through a single cable connection. In the predicate devices, two images may be created by several methods, including viewing the surgical site through two different optical arrays, splitting a single image on the basis of color, or illuminating the surgical site with alternating wavelengths of light. The two channel images may then be transmitted as separate signals using separate cables. However, the questions of safety and effectiveness, namely - does the optical system permit the generation of two channel images and can those images be transmitted to a processing unit that can generate stereo images - are the same for the Elran01 system and the predicate devices. Therefore, these minor differences in technological characteristics do not raise any new questions of safety or effectiveness.

Conclusion

Envision's Elran01 system has the same intended use and similar indications for use, principles of operation, and technological characteristics as the Intuitive Surgical Stereo View system, the Richard Wolf Laparoscope, and the Karl Storz Laparocam. The minor technological differences between the Elran01 system and the class II predicate devices, including the method of two-channel image generation and transmission, do not raise any new questions of safety or effectiveness. Thus, the Elran01 system is substantially equivalent to marketed devices intended viewing internal surgical sites during general endoscopic and laparoscopic surgical procedures.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 4 2000

Envision Advanced Medical System Ltd.
c/o Mr. Gerard J. Prud'homme
Hogan & Hartson, L.L.P.
555 Thirteenth Street, N.W.
Washington, D.C. 20004

Re: K002431
Trade Name: ELRAN 01 Stereoscopic Laparoscope
Regulatory Class: II
Product Code: GCJ
Dated: August 8, 2000
Received: August 8, 2000

Dear Mr. Prud'homme:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its ~~toll-free~~ number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K002431

Device Name: ELRAN 01 Stereoscopic Laparoscope

Indications for Use:

The Elran01 system is intended viewing internal surgical sites during general endoscopic and laparoscopic surgical procedures.

(PLEASE DO NOT ~~WRITE~~ BELOW THIS LINE - ~~CONTINUE ON~~ ANOTHER ~~PAGE IF NEEDED~~

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002431

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____
(Optional Format 1-2-96)